Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume XI Issue 9 October 2006

MTS Inspection Notification Changes

by Lori Hudson, DOH/LQA

On May 31, 2006, the Government Accountability Office (GAO) released a report on its audit of the federal CLIA program. One of GAO's recommendations was that laboratory inspections should be unannounced. Several accrediting organizations such as the College of American Pathologists and the Joint Commission on Accreditation of Healthcare Organizations have changed their inspection process so that their surveys are unannounced.

The CMS CLIA program has determined that unannounced inspections of smaller facilities are difficult since the facility may be closed on the day chosen for the inspection, or appropriate personnel may not be available. Therefore, CMS has directed that surveys performed by the CLIA staff be scheduled with a maximum of **two-weeks notice** prior to the survey. Washington, as an exempt state, has also been asked to implement this policy.

Since the Medical Test Site (MTS) licensing law was effective in 1990, Washington State has chosen to announce all routine surveys for laboratories. However, the MTS program will implement the new **two-week survey notification timeframe** to comply with the CMS CLIA program directive. Some of the questions and/or concerns about this new notification policy are answered below.

Q: Why has Washington State continued to perform announced surveys when other agencies are performing unannounced surveys?

A: Announcing surveys ensures that the appropriate personnel are available and minimizes impact to patient care.

Q: How will this change how my surveys are arranged?

A: There will be no difference except that your surveyor will call to arrange the survey a maximum of two weeks prior to your survey.

Q: Will my survey continue to occur on the same 2-year anniversary date?

A: Yes. Our department will continue to perform routine laboratory surveys every two years. CMS has requested that we revise our survey scheduling so that all surveys be performed within 6 months prior to the survey anniversary date (the date of last survey). The MTS program will implement this directive.

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Inside This Issue

Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

Anemia	Lipid Screening
ANA	PAP Smear
Bioterrorism Event Mgmt	Point-of-Care Testing
Bleeding Disorders	PSA
Chlamydia	Rash Illness
Diabetes	Red Cell Transfusion
Group A Strep Pharyngitis	Renal Disease
Group B Streptococcus	STD
Hepatitis	Thyroid
HIV	Tuberculosis
Infectious Diarrhea	Urinalysis
Intestinal Parasites	Wellness

DOT Packaging & Shipping Regulation Changes

by Laura Kentala, DOH/PHL

In an effort to become compatible with the international shipping community, the US Department of Transportation (DOT) has developed what they call the "harmonization" of regulations. On June 2, 2006, DOT published the new regulations for packaging and shipping biological substances in the Federal Register. This article will discuss some of the most important changes to 40 CFR Parts 171, 172, 173.

The most significant change for laboratories to comply with will be DOT's elimination of the categorizing of biological substances (both animals and humans) by Risk Groups. These changes apply to all types of shipping transportation with the **exception** of the US Postal Service (USPS). Unfortunately, USPS will continue to use the Risk Groups for categorizing infectious substances. Your Lab will have to continue to use the Risk Group categories when using the US mail system for shipping specimens. Hopefully, in the future, the USPS will harmonize with others in the shipping community to make it easier for laboratories to comply with shipping requirements.

DOT has changed the original four Risk Groups to Category A and Category B. These categories are the same ones that have been used for air transportation for the past few years. The definition of Category A is "An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals." Infectious substances in Category A are assigned to UN 2814 (affecting humans) or UN 2900 (affecting animals only). A complete list of Category A organisms is included in the Federal Register update of June 2, 2006. A Category B infectious substance is one that does not meet the criteria for inclusion in Category A. A Category B infectious substance may not cause permanent disability or life-threatening or fatal disease to humans or animals when exposure to it occurs.

The second major change that DOT made is the elimination of the term "Diagnostic Specimen." Like the grouping change, this will go into effect October 1, 2006, and like the grouping change, this does not affect USPS packages. Instead of using Diagnostic Specimen, the new labeling will have to say "Biological Substance, Category B." This is a much better term to use because it covers a broader category of samples and will save the packager time and effort.

Samples that are of unknown infectious substance can be shipped for testing as Category B, infectious substance. This means they will still be triple packed, with a rigid outer package. There must be sufficient absorbent material for the primary and secondary containers such that there is no breakage of the primary container. The package must have been tested to pass the 1.2 meter drop test with no leakage. Labeling must include the label stating "Biological Substance, Category B" and must have the diamond shaped UN3373 label adjacent to it.

Biological Substance Category B organisms will require name, address, and telephone number of person knowledgeable about the substance on a written document such

ELABORATIONS is a free monthly publication of the Washington State Department of Health (DOH) Public Health Laboratories (PHL) and Office of Laboratory Quality Assurance (LQA).

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NOTE: Letters to the editor may be published unless specified otherwise by the author.

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DOH home page: http://www.doh.wa.gov
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DOT Regulation Changes, continued from page 2

as the bill of lading or waybill **or** outer package. This person should be available during the company's administrative office hours to provide information about how to respond to emergencies or releases involving the package and any first aid. Notice the change: if the information is on the paper work, it will be inside the package and then is not required on the outer container.

A major change in the requirements of the outer package for both Category A and B is that it now must be made of a rigid material. That means no envelopes even if they are made of a leak-proof material. The outer package must be capable of withstanding a 4-foot drop with no leakage from the primary container. A requirement for absorbent material to be included in the package is now required for solids that may become liquid during transport.

There are more shipping changes included in this regulation update and it is recommended that you read the entire document regulation changes to see if any of these items are handled by your laboratory. For complete information regarding the new regulations, you can download a copy of the June 2, 2006 Federal Register from the DOT website at http://hazmat.dot.gov/regs/rules/final/71fr/docs/71fr-32243.pdf.

The next Shipping Infectious Materials class is scheduled at the PHL in Shoreline WA on November 8, 2006.

MTS Inspection Notification Changes, cont'd from page 1

Q: What if there are objections to the date and time of the proposed survey?
A: Although laboratories should envision being "survey-ready" at all times, your surveyor can assist you with scheduling the survey to best meet your needs.

Q: Does Washington State ever perform unannounced surveys?
A: Yes. Our department performs unannounced surveys for complaints or for any other reason that an immediate visit is required.

13th Annual Clinical Laboratory Conference

The 2006 Washington Clinical Laboratory Conference will be held at the Doubletree Hotel at Seattle-Tacoma International Airport on November 13, 2006. This annual conference provides the opportunity for laboratory managers and staff to hear national speakers discuss current issues in health care and how they affect the laboratory industry.

Dennis Weissman, President of Dennis Weissman & Associates, LLC, will open the conference with a session titled "Political & Regulatory Climate for the Laboratory Sector: Key Trends & Strategic Implications." Tom Allerding, MD from Sacred Heart Medical Center in Spokane, will present "Estimated Glomerular Filtration Rate (eGFR) and the Early Detection of Chronic Kidney Disease."

Michael Astion, MD, PhD from the University of Washington, will present "Improving the Utilization of Laboratory Tests Using Carrots and Sticks." To round out the day, Marcia Goldoft, MD, Medical Epidemiologist with the Washington State Department of Health (DOH), and Romesh Gautom, PhD, Director of the DOH Public Health Laboratories, will provide an update on "Influenza - Seasonal, Avian, and Pandemic."

If you have not received a flyer for the conference, please contact Leonard Kargacin at (206) 418-5416 or at leonard.kargacin@doh.wa.gov.

NOTE THE LOCATION CHANGE FOR THE 2006 CONFERENCE: This year, the conference will be held at the Doubletree Hotel at Seattle-Tacoma International Airport.

13th Annual Clinical Laboratory Conference

November 13, 2006
8:00 a.m. - 4:30 p.m.

Seattle Doubletree Hotel at SeaTac International Airport

If you have not received a copy of the program, contact Leonard Kargacin:
phone: (206) 418-5416
e-mail: leonard.kargacin@doh.wa.gov

The program will be available from the LQA website:
http://www.doh.wa.gov/hsqa/fsl/lqa_updates.htm.

Calendar of Events

PHL Training Classes:
(http://www.doh.wa.gov/ehsphl/phl/training/train.htm)

Shipping Infectious Substances
November 8 Shoreline

Northwest Medical Laboratory Symposium
October 18-21 Portland

13th Annual Clinical Laboratory Conference
November 13 Seattle

2006 WSSCLS/NWSSAMT Spring Meeting
April 26-28, 2007 Kennewick

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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